DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/08 has been entered.

An amendment filed 1/29/08 amended claims 1-3, 4-10, 12, 15, 25, and 28, and canceled claims 11 and 32.

Claims examined on the merits are 1-3, 5-10, 12, 15 and 25-31, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-10, 12, 15 and 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support is not found in the specification for the film being adapted for "subsequent removal from a wound bed" as required by amended claim 1 in line 2. The specification fails to disclose that the polymeric film should to be adapted for removal from a wound bed.

Response to Arguments

The amendment refers to the specification (page 21, lines 10 to 11) to support removal of the film from a wound bed. However, separating the carrier polymer from the wound bed disclosed in this portion of the specification is to determine the degree of transfer of keratinocytes to the wound bed. This does not support that the polymer was "adapted" for removal from the wound bed after being applied to the wound bed. Additionally, this does not support that when using the carrier polymer to treat a wound, the carrier polymer was to be removed after treatment. The specification discloses (page 21, lines 13-15) that a carrier polymer that is less well adhered to the wound bed indicates a lesser degree of cell transfer. This disclosure indicates that the polymer carrier was designed to adhere to wound bed rather than for removal from the wound bed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-10, 12, 15 and 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1 of claim 1, "adapted for application" is uncertain as to meaning and scope since the feature of the polymeric film that results in the film being adapted is unclear. The difference in a film that is adapted for application and a film that is not adapted for application is uncertain.

Reciting "obtainable" in line 3 of claim 1, makes the claim unclear as to whether plasma polymerization is used to prepare the cell culture surface and the surface contains the carboxylic acid functionality. If plasma polymerization is to be used in preparing the surface, "obtainable" should be changed to --- obtained ---.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-10, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by France et al (C2 on form 1449).

The claims are drawn to a polymeric film adapted for application to and subsequent removal from a wound bed of an acute or chronic cutaneous wound wherein the film has integral therewith, or applied thereto, a cell culture surface having a carboxylic acid functionality

of at least 5% to which at least one keratinocyte is attached, which keratinocyte is capable of detachment from the culture surface and transfer to wound bed upon contact with the wound bed. In dependent claims, the cell culture surface can be prepared by plasma polymerization of acrylic acid or a copolymer of acrylic acid and 1,7-octadiene to coat a substrate. The surface can have a carboxylic acid functionality of 5-20% or greater than 20%. Also claimed are methods for treatment of cutaneous wounds by using the polymeric film.

France et al disclose attachment of human keratinocytes to plasma copolymers (PCPs) of acrylic acid/octa-1,7-diene and allyl amine/octa-1,7-diene. The copolymer is deposited on tissue culture wells or aluminum foil (page 38, left col, line 6) to provide a coating (page 38, left col, line 3 under "Cell attachment assay", and page 39, right col, line 3 under "Keratinocyte culture on PCPs containing carboxylic acid groups") that is a film (line 3 of abstract (page 37)) to produce a surface containing acid functionality that binds the keratinocytes where the keratinocytes were successfully cultured (first sentence under "Discussion" on page 41). The percent acid functionality can be in the range of 5-20% or greater than 20%. For example, see paragraph bridging pages 37 and 38; under "Cell attachment assay" and under "Characterisation of PCPs" and Table 1 on page 38; under "Discussion" on page 41; and under "conclusions" on page 42. The response of human keratinocytes to natural and synthetic surfaces is of importance in wound care and healing (page 37, right col, first complete paragraph).

A copolymer film containing attached keratinocytes disclosed by France et al is a polymeric film as presently claimed. The copolymer film is inherently capable of application to and removal from a wound bed, and keratinocytes attached to the film are inherently capable of detaching and transferring to a wound bed.

Response to Arguments

The amendment urges that France et al does not disclose a polymeric film adapted for application to and subsequent separation from a wound bed of an acute or chronic cutaneous wound. However, France et al discloses a polymeric film formed as disclosed in the present specification, and the film of France et al is inherently adapted for application to and subsequent separation from a wound bed of an acute or chronic cutaneous wound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over France et al in view of Yanagihara et al (4,693,799).

The claim requires propionic acid as the acid subjected to plasma polymerization to produce the cell culture surface.

France et al is described above.

Yanagihara et al disclose (col 6, lines 44-45 and line 58) producing a plasma polymerized film enriched in hydroxyl or carboxyl groups by plasma polymerizing an acid such as propionic acid.

When producing the copolymer film of France et al, it would have been obvious to use propionic acid in place of acrylic acid since Yanagihara et al suggest that propionic acid will provide the function of acrylic acid by disclosing plasma polymerization of propionic acid to produce a film containing carboxyl groups.

Claim Rejections - 35 USC § 103

Claims 1-3, 6-10, 12, 15 and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over France et al (C2 on form 1449) in view of Mayes et al (6,150,459) and McAuslan (WO 87/05038), and if necessary in further view of Daw et al (C1 on form 1449).

The invention and France et al are described above.

Mayes et al disclose coating the surface of a substrate with a copolymer, seeding the coating with cells, and implanting (col 16, lines 58-65) for tissue engineering (col 16, line 53). Also disclosed is wound-healing application (col 16, line 14). The copolymer coating is in the form of a film (col 5, line 28, col 7, line 1, and col 18, lines 48-52).

McAuslan discloses forming an implant by applying to a substrate a hydrogel layer to which cells bind (page 5, lines 15-29).

Daw et al disclose a plasma copolymer surface of acrylic acid/1,7 octadiene and attachment of osteoblast-like cells to the copolymer surface. For example, see page 1718, under "Experimental procedure"; paragraph bridging the columns and Figure 3 on page 1720; Figures 5 and 6 on page 1722; under "Discussion" on page 1723; and under "Conclusions" on page 1724.

It would have been obvious to apply the keratinocyte-binding copolymer of France et al to a substrate as a film as suggested by Mayes et al providing an implant by coating a copolymer film on substrate and binding cells, and McAuslan forming an implant by applying a cell-binding polymer to a substrate. The resultant copolymer film on a substrate will be a polymeric film as presently claimed. The film will inherently be capable of application to and subsequent removal from a wound bed of an acute or chronic cutaneous wound, and will be inherently be capable of transferring attached keratinocytes to a wound bed. Using the polymeric film containing bound kertatinocytes to treat wounds as in dependent claims 25-31

would have been obvious from France et al disclosing that response of keratinocytes to surfaces is important in wound care and healing (page 37, right col, first complete paragraph), and Mayes et al disclosing wound-healing application of cells bound to a copolymer film. Daw et al further disclose attachment of cells to plasma copolymer surfaces of acrylic acid/1,7 octadiene, and if needed would have further suggested the present invention. Copolymer characteristics and other conditions of dependent claims are disclosed by the references, or are not sufficiently different to be unobvious from copolymer characteristics and conditions disclosed by the references.

Response to Arguments

The amendment urges that the references do not disclose a polymeric film in accordance with amended claim 1. However, Mayes et al discloses providing a copolymer coating on a substrate as a film, and it would have been obvious to provide the copolymer coating of France et al as a film to obtain the expected function of a film. The arguments directed to Mayes et al, McAuslan and Daw et al are noted. However, these references are applied in combination with France et al, and the invention becomes the references are considered together rather than each alone. The references have the similarity of attaching cells to a coating on a substrate, and this similarity would have made the references combinable.

Claim Rejections - 35 USC § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-3, 6-12, 15 and 25-31

above, and further in view of Yanagihara et al (4,693,799) for the type of reasons set forth above when applying Yanagihara et al.

When producing copolymer coating of France et al as a film as set forth above, it would have been obvious to use propionic acid in place of the acrylic acid of France et al since Yanagihara et al suggest that propionic acid will provide the function of acrylic acid by disclosing plasma polymerization of propionic acid to produce a film containing carboxyl groups.

Response to Arguments

The amendment urges that Yanagihara et al do not supply elements stated to be missing in the rejection above. However, for reasons set forth above, elements are not missing that will make the claimed invention unobvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
4/11/08